DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Silver Spring, MD 20993

DMF 035936

DMF ACKNOWLEDGEMENT

SUNPURE EXTRACTS PVT. LTD.
ATTN:
E-25, INDUSTRIAL AREA
SIKANDRABAD (U.P.) 203205, INDIA

Dear Sir,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER	035936
ASSIGNED: DATE OF	MAY 18, 2021
SUBMISSION: DMF TYPE:	II
SUBJECT (TITLE):	LUTEIN POWDER 20% (ZEAXANTHIN 4%)
HOLDER:	SUNPURE EXTRACTS PVT. LTD.
SUBMITTED BY:	SUNPURE EXTRACTS PVT. LTD.

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs

The holder of the DMF is responsible for compliance with 21 CFR314.420 as interpreted in "The Guideline for Drug Master Files" at https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf